How do I know which premarket regulatory requirements apply to my reprocessed device?

The device classification of a reprocessed SUD determines if, when, and what type of premarket submission is required.

- If your reprocessed SUD is classified as **class I or class II and is exempt**, no premarket submission is required.
- If your reprocessed SUD is classified as **class I or class II and is not exempt**, a premarket notification, known as a 510(k), is required.
- If your reprocessed SUD is classified as **class III**, generally a premarket approval application, known as a PMA, is required.

How do I register and list reprocessed SUDs?

A hospital that reprocesses SUDs must register with FDA and list every type of reprocessed device. For additional information, see "CDRH Guidance for Industry: Instructions for Completion of Medical Device Registration and Listing Forms FDA-2891, 2891a, and 2892" at www.fda.gov/cdrh/dsma/rlman.html.

What is required for device labeling?

FDA has general labeling requirements regarding the name and place of manufacture and inclusion of adequate directions for use. See "Labeling Regulatory Requirements for Medical Devices" at www.fda.gov/cdrh/dsma/470.pdf.

How do I report an adverse event with an SUD?

Hospitals that reprocess SUDs are subject to the manufacturer reporting requirements as well as the user facility reporting requirements (21 ***CFR*** 803 Subpart E). In addition, they must adhere to the user facility reporting requirements for all other medical devices that they use. See guidance documents on MDR at www.fda.gov/cdrh/mdr.html.

What is "device tracking" and how will a hospital know when to track an SUD?

A hospital that reprocesses SUDs is **not** subject to the Medical Device Tracking regulation (21 ***CFR*** Part 821) **unless and until** FDA issues a direct order to track a specific device being reprocessed. See "Guidance on Medical Device Tracking" at www.fda.gov/cdrh/modact/tracking.pdf.

If there are problems with certain reprocessed SUDs and they are removed from inventory, must FDA be notified?

A hospital that reprocesses SUDs must report to FDA, within a specified time, certain types of device corrections and removals. The terms "correction" and "removal" are defined in 21 ***CFR*** 806.2(e) and 806.2(i).

Need more information?

In addition to the guidance documents and resources referenced in this brochure, see FDA's Reuse Homepage at www.fda.gov/cdrh/reuse/index.shtml. This web site also includes a list of sterility and cleaning standards and related documents for medical devices. To contact FDA's Division of Small Manufacturers Assistance (DSMA), call 301-443-6597 or 1-800-638-2041 or send an e-mail to dsma@cdrh.fda.gov. Requests for publications may be submitted by e-mail or by FAX to 301-443-8818. You also are encouraged to visit **Device Advice** at www.fda.gov/cdrh/devadvice/.

Center for Devices and Radiological Health
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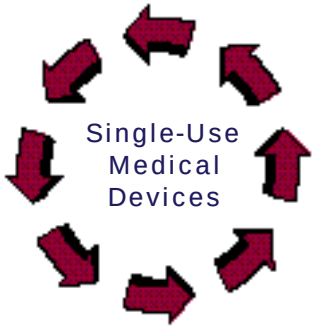
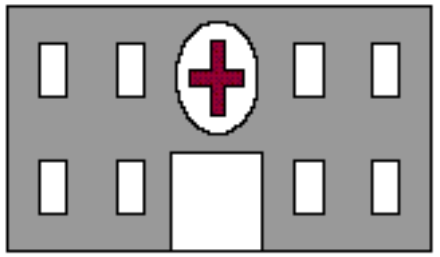
Reprocessing of Single-Use Medical Devices by Hospitals





REPROCESSING OF SINGLE-USE MEDICAL DEVICES BY HOSPITALS

Because insufficient data exist regarding the safety of reprocessing single-use devices (SUDs), the U.S. Food and Drug Administration (FDA) announced on August 14, 2000, it will regulate hospitals engaged in reprocessing SUDs in the same way that the agency regulates device manufacturers.

We strongly encourage you to read the "Guidance on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," because it describes in detail the requirements of the reuse policy. The document is available at www.fda.gov/cdrh/comp/guidance/1168.pdf.

Are all healthcare facilities that reprocess SUDs subject to the requirements?

At this time, FDA is limiting its focus to **hospital** and third-party reprocessors. In the future, FDA will examine whether other establishments that reprocess SUDs should be included.

Does the SUD enforcement guidance apply to all reprocessed SUDs?

It does not apply to:

- permanently implantable pacemakers,
- "open-but-unused" single-use devices, and
- hemodialyzers. The reuse of hemodialyzers is addressed in "Guidance for Hemodialyzer Reuse Labeling" of October 6, 1995, at www.fda.gov/cdrh/ode/dilreuse.pdf.

Which devices are known to be reprocessed?

Some examples of reprocessed SUDs are surgical saw blades, balloon angioplasty (PTCA) catheters, laparoscopy scissors, and endotracheal tubes. For the complete list of SUDs known to be reprocessed, see Appendix A of the guidance.

What are the regulatory requirements under the Food, Drug, and Cosmetic Act that hospitals must meet if they reprocess SUDs?

The regulatory requirements include:

- establishment registration and device listing (21 *Code of Federal Regulations* (***CFR***) Part 807);
- good manufacturing practice (GMP) under the Quality System regulation (21 ***CFR*** 820);
- device labeling (21 ***CFR*** Part 801);
- submission of adverse events reports under the Medical Device Reporting (MDR) regulation (21 ***CFR*** 803);
- medical device tracking (21 ***CFR*** Part 821);
- corrections and removals (21 ***CFR*** Part 806);
- premarket requirements (21 ***CFR*** Parts 807 and 814).

What is good manufacturing practice under the Quality System regulation?

Hospitals that reprocess SUDs must meet the Quality System (QS) regulation for medical devices (21 ***CFR*** Part 820). The QS regulation requires a reprocessing hospital to have a quality assurance program or quality system that is appropriate for the specific type of device being reprocessed and that meets the requirements of the QS regulation. FDA monitors compliance with the QS regulation during inspection of the facility. All registered hospitals that reprocess SUDs will be subject to periodic FDA inspection.

The requirements under the QS regulation are intended to assure that continuing quality is incorporated into the devices during reprocessing, rather than by testing and removing defective devices to achieve quality. For more information, see www.fda.gov/cdrh/dsma/cgmphome.html.

When must a hospital that reprocesses SUDs meet the regulatory requirements?

For hospital reprocessors, FDA is allowing a one year phase-in period for active enforcement of the **non-premarket** requirements. FDA intends to enforce **premarket submission requirements** by:

- February 14, 2001, for **class III** devices;
- August 14, 2001, for non-exempt **class II** devices;
- February 14, 2002, for non-exempt **class I** devices.

What are class I, II, and III devices?

In general, the ***CFR*** designates a 3-tiered device classification system. Class III devices are generally considered to pose the greatest potential risk to the health of the public and require the most regulation, while class I devices pose the lowest potential risk and require the least regulation. A device's classification is available in 21 ***CFR*** Parts 862-892 or by searching FDA's database at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm.